

## § 862.1040

## 21 CFR Ch. I (4–1–01 Edition)

### § 862.1040 Aldolase test system.

(a) *Identification.* An aldolase test system is a device intended to measure the activity of the enzyme aldolase in serum or plasma. Aldolase measurements are used in the diagnosis and treatment of the early stages of acute hepatitis and for certain muscle diseases such as progressive Duchenne-type muscular dystrophy.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2305, Jan. 14, 2000]

### § 862.1045 Aldosterone test system.

(a) *Identification.* An aldosterone test system is a device intended to measure the hormone aldosterone in serum and urine. Aldosterone measurements are used in the diagnosis and treatment of primary aldosteronism (a disorder caused by the excessive secretion of aldosterone by the adrenal gland), hypertension caused by primary aldosteronism, selective hypoaldosteronism, edematous states, and other conditions of electrolyte imbalance.

(b) *Classification.* Class II.

### § 862.1050 Alkaline phosphatase or isoenzymes test system.

(a) *Identification.* An alkaline phosphatase or isoenzymes test system is a device intended to measure alkaline phosphatase or its isoenzymes (a group of enzymes with similar biological activity) in serum or plasma. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

(b) *Classification.* Class II.

### § 862.1060 Delta-aminolevulinic acid test system.

(a) *Identification.* A delta-aminolevulinic acid test system is a device intended to measure the level of delta-aminolevulinic acid (a precursor of porphyrin) in urine. Delta-aminolevulinic acid measurements are used in the diagnosis and treatment of lead poisoning and certain porphyrias

(diseases affecting the liver, gastrointestinal, and nervous systems that are accompanied by increased urinary excretion of various heme compounds including delta-aminolevulinic acid).

(b) *Classification.* Class I (general controls). The device is exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2305, Jan. 14, 2000]

### § 862.1065 Ammonia test system.

(a) *Identification.* An ammonia test system is a device intended to measure ammonia levels in blood, serum, and plasma. Ammonia measurements are used in the diagnosis and treatment of severe liver disorders, such as cirrhosis, hepatitis, and Reye's syndrome.

(b) *Classification.* Class I.

### § 862.1070 Amylase test system.

(a) *Identification.* An amylase test system is a device intended to measure the activity of the enzyme amylase in serum and urine. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

(b) *Classification.* Class II.

### § 862.1075 Androstenedione test system.

(a) *Identification.* An androstenedione test system is a device intended to measure androstenedione (a substance secreted by the testes, ovary, and adrenal glands) in serum. Androstenedione measurements are used in the diagnosis and treatment of females with excessive levels of androgen (male sex hormone) production.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2305, Jan. 14, 2000]

### § 862.1080 Androsterone test system.

(a) *Identification.* An androsterone test system is a device intended to measure the hormone androsterone in serum, plasma, and urine. Androsterone measurements are used in the